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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,591	BOWDISH ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,23,24,26-37,73,74 and 85-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,23,24,26-37,73,74 and 85-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/18/03 and 6/3/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner for your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Walter Schlapkohl in Art Unit 1636 whose contact information can be found in the conclusion of this Office action.

Receipt is acknowledged of the papers filed 1/23/2006 in which new drawings were filed and of the papers filed 12/19/2005 in which claims 1, 85 and 92 were amended. Claims 1-6, 23-24, 26-37, 73-74 and 85-96 are pending and under examination in the instant application.

Any rejections made in the previous Office Action not recited within the instant Office Action are hereby withdrawn.

Drawings

The drawings were received on 1/23/2006. These drawings are not acceptable.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: specifically, Figure 7 shows the reference character 118 which is not mentioned in description. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the

specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 23, 28-36, 85, 88-89 and 92-94 are objected to because of the following informalities: claims 23, 28-36, 85, 88-89 and 92-94 recite "downstream primer" instead of "downstream primer sequence."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 23-24, 26-36, 73, 85-89 & 92-94, and therefore dependent claims 6, 37, 74, 90-91 & 95-96, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 23-24, 26-36, 85-89 and 92-94 recite the phrase "being capable of annealing" in reference to primer sequences and/or collar sequences which are designed to anneal to a portion of a polypeptide encoding nucleic acid. Claims 1-5, 23-24, 26-36, 85-89 and 92-94 are vague and indefinite in that the metes and bounds of such a primer sequence or collar sequence are unclear. Does Applicant intend to encompass only those primer and/or collar sequences which anneal to a complementary nucleic acid under stringent conditions, or does Applicant intend a much broader interpretation, including nucleic acid sequences which may only anneal to one or two bases under low stringency conditions?

Claim 24 recites "[a] plasmid as in claim 23 wherein the upstream collar sequence is capable of annealing to a portion of the mRNA encoding a framework region of an antibody" in lines 1-2. Claim 24 is vague and indefinite in that "the mRNA encoding a framework region of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a framework region of an antibody" in claim 23.

Claim 26 recites "[a] plasmid as in claim 23 wherein the upstream collar sequence is capable of annealing to a portion of the mRNA encoding a framework region associated with a light chain of antibody" in lines 1-3. Claim 26 is vague and indefinite in that "the mRNA encoding a framework region associated with a light chain of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a framework region associated with a light chain of an antibody" in claim 23.

Claim 27 recites "[a] plasmid as in claim 23 wherein the upstream collar sequence is capable of annealing to a portion of the mRNA encoding a framework region associated with a heavy chain of an antibody" in lines 1-3. Claim 27 is vague and indefinite in that "the mRNA encoding a framework region associated with a heavy chain of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a

framework region associated with a heavy chain of an antibody" in claim 23.

Claim 28 recites "[a] plasmid as in claim 23 wherein the downstream primer sequence is capable of annealing to a portion of the mRNA encoding a constant region of an antibody" in lines 1-2. Claim 28 is vague and indefinite in that "the mRNA encoding a constant region of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a constant region of an antibody" in claim 23.

Claim 29 recites "[a] plasmid as in claim 23 wherein the downstream primer sequence is capable of annealing to a portion of the mRNA encoding a constant region associated with a light chain of an antibody" in lines 1-3. Claim 29 is vague and indefinite in that "the mRNA encoding a constant region associated with a light chain of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a constant region associated with a light chain of an antibody" in claim 23.

Claim 30 recites "[a] plasmid as in claim 23 wherein the downstream primer is capable of annealing to a portion of the mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a light chain of an antibody" in lines 1-3. Claim 30 is vague and indefinite in

that "the mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a light chain of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a light chain of an antibody" in claim 23.

Claim 31 recites "[a] plasmid as in claim 23 wherein the downstream primer is capable of annealing to a portion of the mRNA encoding a constant region associated with a heavy chain of an antibody" in lines 1-3. Claim 31 is vague and indefinite in that "the mRNA encoding a constant region associated with a heavy chain of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a constant region associated with a heavy chain of an antibody" in claim 23.

Claim 32 recites "[a] plasmid as in claim 23 wherein the downstream primer is capable of annealing to a portion of the mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a heavy chain of an antibody" in lines 1-3. Claim 32 is vague and indefinite in that "the mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a heavy chain of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a framework two (FR2), framework

three (FR3) or framework four (FR4) region associated with a heavy chain of an antibody" in claim 23.

Claim 33 recites "[a] plasmid comprising: a downstream primer sequence comprising SEQ ID NO: 4 incorporated into the plasmid, the downstream primer being capable of annealing to a first portion of mRNA encoding at least a framework region of an antibody; an upstream collar sequence incorporated into the plasmid, the upstream collar sequence being capable of annealing to a second portion of the mRNA encoding at least a portion of an antibody" in lines 1-7. Claim 33 is vague and indefinite in that there is no clear and positive antecedent basis for "the mRNA encoding at least a portion of an antibody" within the claim.

Claim 73 recites "[a] plasmid as in claim 1 wherein two restriction sites that are the same or different are located between the downstream primer and upstream collar sequences" in lines 1-2. Claim 73 is vague and indefinite in that the phrase "the downstream primer and upstream collar sequences" lacks clear and positive antecedent basis. There are no "downstream primer and upstream collar sequences" in claim 1.

Claim 86 recites "[a] plasmid as in claim 85 wherein the upstream collar sequence is capable of annealing to a portion of the coding sequence of the mRNA encoding at least a portion of a

framework region of a light chain associated with an antibody" in lines 1-3. Claim 86 is vague and indefinite in that "the mRNA encoding at least a portion of a framework region of a light chain associated with an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding at least a portion of a framework region of a light chain associated with an antibody" in claim 85.

Claim 87 recites "[a] plasmid as in claim 85 wherein the upstream collar sequence is capable of annealing to a portion of the coding sequence of the mRNA encoding at least a portion of a framework region of a heavy chain associated with an antibody" in lines 1-3. Claim 87 is vague and indefinite in that "the mRNA encoding at least a portion of a framework region of a heavy chain associated with an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding at least a portion of a framework region of a heavy chain associated with an antibody" in claim 85.

Claim 88 recites "[a] plasmid as in claim 85 wherein the downstream primer is capable of annealing to a portion of the coding sequence of the mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a light chain of an antibody" in lines 1-4. Claim 88 is vague and indefinite in that "the mRNA encoding a framework two

(FR2), framework three (FR3) or framework four (FR4) region associated with a light chain of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a light chain of an antibody" in claim 85.

Claim 89 recites "[a] plasmid as in claim 85 wherein the downstream primer is capable of annealing to a portion of the coding sequence of the mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a heavy chain of an antibody" in lines 1-4. Claim 89 is vague and indefinite in that "the mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a heavy chain of an antibody" lacks clear and positive antecedent basis. There is no "mRNA encoding a framework two (FR2), framework three (FR3) or framework four (FR4) region associated with a heavy chain of an antibody" in claim 85.

Claim 92 recites "an upstream collar sequence incorporated into the plasmid, the upstream collar sequence being capable of annealing to at least a second portion of the coding sequence of the mRNA encoding at least a portion of a framework region associated with the antibody" in lines 5-7. Claim 92 is vague

and indefinite in that "the mRNA encoding at least a portion of a framework region associated with the antibody" lacks clear and positive antecedent basis within the claim.

Claim 93 recites "[a] plasmid as in claim 92 wherein the downstream primer is capable of annealing to a portion of the coding sequence of the mRNA encoding a constant region associated with a light chain of an antibody" in lines 1-3. Claim 93 is vague and indefinite in that "the mRNA encoding a constant region associated with a light chain of an antibody" lacks clear and positive antecedent basis. No "mRNA encoding a constant region associated with a light chain of an antibody" appears in claim 92.

Claim 94 recites "[a] plasmid as in claim 92 wherein the downstream primer is capable of annealing to a portion of the coding sequence of the mRNA encoding a constant region associated with a heavy chain of an antibody" in lines 1-3. Claim 94 is vague and indefinite in that "the mRNA encoding a constant region associated with a heavy chain of an antibody" lacks clear and positive antecedent basis. No "mRNA encoding a constant region associated with a heavy chain of an antibody" appears in claim 92.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 23-24, 26-37, 73-74 and 85-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

The claims are drawn to plasmids comprising an incorporated primer sequence and an incorporated collar sequence, said primer and collar sequences being capable of annealing to at least a respective first and second portion of an antibody portion encoding nucleic acid, the portions being separated by at least 20 nucleotides, and further wherein the primer sequence and collar sequence adjoin to one another to create at least one restriction site. The claims are further drawn to host cells transformed with such plasmids. Thus, the claims encompass

plasmids with an incorporated primer sequence (undefined) and an incorporated collar sequence (undefined) as long as any portion of the primer sequence and any portion of the collar sequence can anneal under any conditions to different portions of the coding region of a nucleic acid encoding an antibody or a portion of an antibody wherein the portions are separated by at least 20 nucleotides. The claims do not provide any structural information with regard to the primer and collar sequences capable of annealing under any conditions to different portions of the coding region of a nucleic acid encoding an antibody or a portion of an antibody or to different portions of the coding region for any polypeptide such that the vector can be used to clone the nucleic acid of interest. Thus, the rejected claims comprise a set of nucleic acid sequences that are defined by their function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes on page 18 the phagemid vector pRL5-CAT, which was

modified between the SacI and XbaI sites to contain the FR1 collar sequence (SEQ ID NO: 3) immediately adjacent to the Kappa constant region primer sequence (SEQ ID NO: 4). The specification further notes that "the junction of the two annealing sequences in this case forms a SmaI restriction site" (page 18). The specification also describes such a vector which was modified between the XhoI and SpeI sites to contain the FR1 collar sequence and the heavy chain CH1 constant region primer sequence (page 19). The junction of the two sequences in this case forms a HincII restriction site (page 19 and Figure 6B). No description is provided of a primer sequence which is located upstream of the collar sequence encompassed by claims 1-6. No description is provided of which primer sequences and which collar sequences are capable of annealing to which antibodies, much less which portions of those antibodies to which they are capable of annealing (Claims 1-6, 23-24, 26-37, 73-74 and 85-96) such that the vector can be utilized to clone the polypeptide coding region of interest.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of two nucleic acid sequences comprising primer and collar sequences capable of annealing to different portions

of the coding region of a nucleic acid encoding an antibody or a portion of an antibody such that the vector can be used to clone a nucleic acid of interest. The results are not necessarily predictive of any other sequences capable of annealing to different portions of the coding region of a nucleic acid encoding an antibody or a portion of an antibody such that the vector can be used to clone a nucleic acid of interest. Thus it is impossible to extrapolate from the example described herein those nucleic acid molecules that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of vectors comprising primer and collar sequences capable of annealing to different portions of the coding region of a nucleic acid encoding an antibody or a portion of an antibody such that the vector can be used to clone a nucleic acid of interest.

Given the very large genus of nucleic acid molecules encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to the vector sequences capable of fulfilling the claim limitations of claims 1-6, 23-24, 26-37, 73-74 and 85-96, the

skilled artisan would not have been able to describe the broadly claimed genus of plasmids comprising primer and collar sequences capable of annealing to different portions of the coding region of a nucleic acid encoding an antibody or a portion of an antibody such that the vector can be used to clone a nucleic acid of interest. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those nucleic acid sequences that satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1-6, 23-24, 26-37, 73-74 and 85-96.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 23-24, 26-32, 37, 73-74, and 85-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (P.N.A.S., 80:1194-1198, 1983). **This is a new rejection.**

For purposes of this rejection, phrases such as "mRNA encoding at least a portion of an antibody" (e.g., claim 4) or "a portion of the mRNA encoding a framework region" (e.g., claim 26) or "a portion of the mRNA encoding a constant region of an antibody" (e.g., claim 29) used throughout the rejected claims has been given its broadest reasonable interpretation, and as such, the recited phrases include portions which are only a single nucleotide in length as long as the nucleotide falls within the coding sequence of the mRNA. Thus, any primer sequence or collar sequence that is capable of annealing to a polypeptide encoding portion of an mRNA (or other nucleic acid) is also capable of annealing to an "mRNA encoding at least a portion of an antibody" or "a portion of the mRNA encoding a framework region" or "a portion of the mRNA encoding a constant region of an antibody."

Young et al teach a λgt11 expression vector with a unique EcoR1 cloning site within the lacZ coding sequence wherein the lacZ sequences 5′ and 3′ of the EcoR1 site are the respective "collar" and "primer" sequences capable of annealing to at least a first portion of an antibody/constant region/framework region wherein the portions are separated by at least 20 nucleotides in length and separating sequence comprises at least one or two restriction sites (see entire document, especially Figure 1).

Because only a portion (one nucleotide) need anneal and the conditions for the annealing have not been specified, the claim limitations are met by the λgt11 expression vector, regardless of the polypeptide encoding sequence utilized in the annealing as long as the polypeptide encoding sequence comprises at least two separated portions to which a portion of the primer and sequence can anneal, wherein the separated portions are at least 20 nucleotides apart and the separating sequence contains at least (or two, depending upon the claim) restriction sites. Because the primer and collar sequences are those just 5′ and 3′ of the EcoR1 site in the λgt11 expression vector, the primer and collar sequence adjoin to create a restriction site. The λgt11 expression vector was present in a host cell (see Young et al at page 1195, Table 1), thus meeting the claim limitations of claims 6, 37 and 96.

Claims 23-24 and 26-32, 37, 74, 85-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohno et al (Gene 188:175-181, 1997, of record). **This rejection is maintained for reasons of record, but has been slightly altered in order to accommodate Applicant's amendment.**

Kohno et al teach a plasmid construct in Figure 1B that meets the limitations of the instantly rejected claims.

Specifically, the plasmid of Figure 1B has a 5' "primer" sequence capable of binding to a first portion of a nucleic acid encoding the polypeptide known as Rad52 (or any other polypeptide). Kohno et al also teach a 3' "collar" sequence that is capable of binding to a second portion of a nucleic acid sequence encoding Rad52 (or any other polypeptide), wherein the "primer" and "collar" sequences are capable of annealing to a nucleic acid coding sequence in portions of the sequence separated by at least 20 nucleotides and/or wherein such separating sequences comprise one, two or more restriction sites.

Response to Arguments

Applicant's arguments are rendered moot in part by the withdrawal of the rejection *of claims 1-6 and 73* under U.S.C. 35, §102 as anticipated by Kohno et al (of record). However, to the extent that Applicant's arguments are pertinent to the instant rejection under U.S.C. 35, §102 as anticipated by Young et al and as anticipated by Kohno et al, Applicant's arguments are addressed herein.

Applicant argues that Examiner's interpretation of "at least a portion of" is incorrect on the following grounds. First, the specification teaches that the downstream primer and

upstream collar sequences should be of sufficient length to support specific and stable hybridization to the target complementary mRNA and that the specification also teaches that the annealing sequences may individually contain from about 10 nucleotides to about 50 or more nucleotides in length. As such, Applicant argues, the skilled artisan would know the metes and bounds of the term "at least a portion." Second, Applicant argues that in *Phillips v. AWH Corp.*, 2005 WL 1620331 (Fed. Cir. July 12, 2005), the opinion of the *en banc* majority held that "when construing patent claims, a court should **consult the specification** and prosecution history to determine if the patentee intended to use particular terms in ways other than their ordinary meaning." Therefore, Applicant argues, Examiner's "claim construction" is not consistent with the teachings of the specification. Applicant further argues that the Kohno reference fails to meet each and every element as set forth in the claims because Kohno et al do not teach primer collar sequences which adjoin one another to create at least one restriction site as in amended claim 1. In addition, Applicant argues, Kohno et al do not teach the framework region associated with the antibody or the constant region associated with the antibody as recited in claims 85 and 92.

Examiner has considered Applicant's arguments carefully and has respectfully found them unpersuasive on the following grounds. Examiner agrees with Applicant insofar as the claims should be interpreted in light of the specification, particularly when the specification has defined terms in ways other than their ordinary meaning. To that end, Applicant is invited to point out where in the specification Applicant has clearly defined the metes and bounds of "at least a portion of" or "a portion of the mRNA encoding," either in a way other than their ordinary meaning would suggest or otherwise. Preferable embodiments and indefinite instructions which indicate that the primer and collar sequences "should be of sufficient length to support specific and stable hybridization to the target complementary mRNA" are not definitions. Therefore, with no clear and limiting definition in the specification with regard to "at least a portion of" or "a portion of the mRNA encoding," Examiner is left to give the claims their broadest reasonable interpretation. With regard to Applicant's arguments concerning the Kohno et al reference's inability to meet each and every element of the claim, Examiner has found this to be true *after amendment of claim 1* and has therefore withdrawn the rejection under U.S.C. 35, §102 as anticipated by Kohno et al for claims 1-6 and 73 only, as these claims now include the limitation that

the primer and collar sequences adjoin to create at least one restriction site. However, Applicant's assertion that because Kohno et al do not teach the "framework region associated with the antibody" or the "constant region associated with the antibody" as recited in claims 85 and 92, Kohno et al do not teach each and every element of the claims, is found unpersuasive. Kohno et al need not teach a framework region or a constant region of an antibody because the claims only require that the collar and primer sequences be *capable* of annealing to at least a first and second portion of the polypeptide/antibody/constant region/framework portion of a nucleic acid. As stated above, a portion may be as small as one nucleotide; thus the primer sequences of Kohno et al which comprise G, C, T, and A nucleotides need only anneal to any C, G, A, or T nucleotide in the first or second portion of the polypeptide/antibody/constant region/framework portion of the nucleic acid to which the primer and collar sequences are capable of annealing, i.e. with regard to claims 23-24, 26-32, 37, 74, and 85-96, any set of primer and collar sequences will meet this limitation. With regard to claims 1-6, 23-24, 26-32, 37, 73-74, and 85-96, any set of primer and collar sequence will meet this limitation as long as the primer and collar sequences adjoin to create at least one restriction site.

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all

patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

April 12, 2006

NANCY VOGEL
PRIMARY EXAMINER